

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE ST. JUDE MEDICAL, INC.,	:	
SILZONE HEART VALVES PRODUCTS	:	
LIABILITY LITIGATION	:	MDL DOCKET NO. 1396

PRETRIAL ORDER NO. 6

The Court finds that the parties have met and conferred with regard to an order for the preservation of physical evidence.

The parties have agreed that this Order pertains to explanted St. Jude Medical Silzone® coated heart valves and that it supercedes Order No. 1 (Setting Initial Conference) to the extent that Order No. 1 applied to the preservation of explanted Silzone® coated mechanical heart valves.

The parties have further agreed to the following:

1. This Order applies to Silzone® coated mechanical heart valves that have been explanted from any person, animal, or in vitro testing environment.

2. Except as otherwise permitted in this Order, St. Jude Medical shall not conduct any testing on explanted Silzone® coated heart valves other than the testing described in the attached Valve Preservation Protocol.

FILED _____
RICHARD D. SLETTEN, CLERK
JUDGMENT ENTD _____
DEPUTY CLERK _____

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3. St. Jude Medical may conduct testing on explanted Silzone® coated heart valves if the testing conforms to the protocol described in the attached Valve Preservation Protocol.

4. St. Jude Medical may conduct testing on explanted Silzone® coated heart valves in addition to the testing described in the attached Valve Preservation Protocol when required by a regulatory agency or ordered by a court; provided, that St. Jude Medical shall give immediate written notice to Plaintiffs' counsel of any such regulatory or court order or request therefor and shall take reasonable lawful steps to postpone such testing until any objections of Plaintiffs' counsel can be interposed and resolved. St. Jude Medical shall permit an expert designated by Plaintiffs' counsel to be present at and to observe any court or agency ordered testing that goes beyond testing permitted under the Valve Preservation Protocol.

5. When St. Jude Medical is asked to return an explanted Silzone® coated heart valve to the hospital or physician who provided it or to the patient from whom the device was explanted, St. Jude Medical will not release the item without either (1) prior receipt of a written statement that the recipient hospital, physician or patient will not perform or permit destructive testing on the device, or (2) a court order. Prior to returning any explanted Silzone® coated heart valve, St. Jude Medical shall notify Plaintiffs in writing of the intended return and provide Plaintiffs with a reasonable

opportunity to inspect such valve. Plaintiffs' inspection may include inspection by an expert designated by Plaintiffs' counsel at such expert's testing facility.

6. When an order is sought either (1) to require or permit St. Jude Medical to conduct testing (destructive or otherwise) on explanted Silzone® coated heart valves other than that described in the attached Valve Preservation Protocol, or (2) to require St. Jude Medical to return an explanted Silzone® coated heart valve to a hospital, physician or patient, St. Jude Medical shall promptly give the Plaintiffs written notice of the requested order.

7. When a regulatory agency requests that St. Jude Medical conduct testing on an explanted Silzone® coated heart valve other than the testing described in the attached Valve Preservation Protocol, St. Jude Medical shall promptly notify the Plaintiffs in writing.

8. St. Jude Medical shall preserve in their present condition and not conduct any testing on explanted Silzone® coated heart valves from in vitro and animal tests related to Silzone® other than the testing that conforms to the attached Valve Preservation Protocol.

9. The Plaintiffs shall preserve in their present condition, or in the condition in which they are subsequently received, and not conduct any testing on any explanted Silzone® coated heart valves other than testing that conforms to the attached Valve

Preservation Protocol. For purposes of any such testing, Plaintiffs shall be entitled to retain their own pathologist.

10. St. Jude Medical shall produce to Plaintiffs no later than March 12, 2002, a complete listing by serial number and model of every explanted Silzone coated heart valve returned to St. Jude Medical, including a statement of (i) the date each such valve was returned, and (ii) whether such valve has been or will be sent to St. Jude Medical's independent pathologist. St. Jude Medical shall supplement this list as it receives additional explanted Silzone valves.

11. St. Jude Medical shall also produce to Plaintiffs no later than March 12, 2002, (i) complete copies of all of the independent pathologist's reports it obtains for any explanted Silzone coated heart valves and (ii) reprints of all photographs taken by St. Jude Medical of any explanted Silzone coated heart valves, clearly labeled or marked to identify the pictured valve. St. Jude Medical shall supplement this production as further valve photographs and pathologist's reports for additional explanted Silzone valves are created and received.

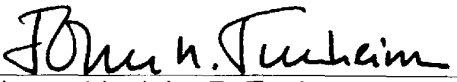
12. Plaintiffs shall have the right, upon 72 hours written notice to St. Jude Medical's lead counsel, to inspect any and all explanted Silzone coated heart valves in St. Jude Medical's possession, custody or control, including inspection and testing by an expert designated by Plaintiffs' counsel at such expert's testing facility. In the event a valve is not on the premises of St. Jude Medical at the time plaintiffs' request an

inspection, then St. Jude Medical shall have fourteen (14) days to reacquire the valve and make it available to plaintiffs for inspection.

13. The provisions of the attached Valve Preservation Protocol are incorporated herein and made a part hereof.

IT IS SO ORDERED:

March 1, 2002


Honorable John R. Tunheim
UNITED STATES DISTRICT JUDGE

VALVE PRESERVATION PROTOCOL

1. Pursuant to its regulatory obligations under 21 CFR 803, and 21 CFR 820.198, St. Jude Medical analyzes returned explanted Silzone® coated heart valves and maintains the explanted valves in specifically designated cabinets in the Field Experience Report (FER) laboratory at the corporate offices of St. Jude Medical in St. Paul, Minnesota. All of the explanted valves and all of the materials and documentation related to investigation or analysis thereof, including, without limitation, all photographs, all x-rays, all samples and slides, all pathologist's reports, and any and all contents of FER files shall be retained while this litigation is pending.

2. Upon notification of a valve explant, a clinical FER administrator opens a file on the explanted valve to document the valve information including the model and serial number, and a code describing the complaint made about the valve, if any. The investigation process typically involves sending out inquiry letters to the hospital or physician to assist in the collection of necessary information to comply with regulatory obligations.

3. If the explanted valve is returned to St. Jude Medical, an FER analyst confirms the serial number and model of the explanted valve, documents the chain of custody by identifying the date received, and then coordinates testing that is required to comply with St. Jude Medical's regulatory obligations. The FER analyst is also

responsible for the storage and preservation of the explanted valves after testing and analysis.

4. St. Jude Medical requires that explanted mechanical heart valves be returned in a specimen container submerged in 10% formalin sterilizing solution. However, explanted valves are returned to St. Jude Medical in various conditions. Some valves are returned in solution and some are not. Some explanted valves have tissue attached and some do not.

5. After an explanted valve is received and the FER analyst documents the model and serial number as well as date received, the FER analyst photographs the valve in the condition in which it was received (i.e. the return packaging). The explanted valve is removed with the tissue, if any, from the packaging and sterilized in a 10% formalin solution for a minimum of 24 hours. This sterilization process does not remove or otherwise materially affect any tissue attached to the valve.

6. Following sterilization, the FER analyst photographs at a minimum the valve inflow and valve outflow aspects using a zoom lens and arranges for the valve to be x-rayed. The photos and x-rays are retained with the FER file.

7. The FER analyst then determines what testing is required based on the reason for explant or the concern raised with respect to the valve, so that a report can be made to the regulators where necessary. Explanted valves require testing that

involves disassembly of the valve only in certain limited circumstances where such testing is necessary and warranted, such as where a concern has been raised with regard to the mechanical function of the valve. However, where the primary concern raised is paravalvular leak or endocarditis, testing will not involve disassembly or mechanical testing. Furthermore, when there is tissue on the explanted valve, regardless of the reason for explant or concern raised, St. Jude Medical will not disassemble the explanted valve or perform mechanical testing.

8. St. Jude Medical has retained Jack L. Titus, M.D., Ph.D., an independent pathologist, to assist in the evaluation of certain returned products, including but not limited to many returned explanted valves (mechanical and biological, Silzone® and conventional). Only pathologists from the Jesse E. Edwards Registry of Cardiovascular Disease, St. Paul Heart & Lung Center, 255 North Smith Avenue, Suite 200, St. Paul, Minnesota 55102, shall perform pathological examinations for St. Jude pursuant to this Protocol, until such time as St. Jude Medical shall give the Plaintiffs written notice of the appointment of a different independent pathologist. The pathologist performs pathological examinations that are intended to assist St. Jude Medical in its efforts to evaluate product returns and in the fulfillment of its regulatory obligations.

9. In the case of explanted Silzone® coated heart valves that are returned to St. Jude Medical, the explanted valves are sent to the retained independent pathologist after the steps listed above (except in some circumstances where there is no notable tissue on the valve). The pathologist examines the valve, sewing cuff, and any tissue present with the valve from a pathological perspective. The pathologist provides a

gross description of the material received. Typically, if there is tissue on the valve, the pathologist will biopsy small portions of the tissue for microscopic analysis; the biopsy will include a small portion of the sub-adjacent sewing cuff. If sufficient tissue is present, the pathologist takes biopsies from two locations around the valve. The tissue biopsies are placed in a cassette(s), and a paraffin tissue block is prepared from which histology sections (slides) are prepared. The valve and remaining tissue are returned intact to the formalin solution. The paraffin block with its tissue is a source for further histology studies and it is preserved at the pathologist's office. St. Jude Medical shall cause the independent pathologist to preserve all such paraffin blocks until further notice to permit the preparation of multiple duplicate slides if requested by Plaintiffs, including, without limitation, unstained duplicates and duplicates stained in the same manner as slides used by the independent pathologist. The pathologist's examination of the tissue/cuff biopsies involves a microscopic (histological) examination of the tissue types, including a search for abnormal reactions. The pathologist's report, including a gross description and the microscopic evaluation, is returned with the explanted valve to St. Jude Medical.

10. The information received from the pathologist is used to prepare reports to the FDA and other regulators, where necessary. The pathologist's reports are retained per St. Jude Medical's internal procedures, as are the explanted valves that the pathologist returns to St. Jude Medical.

11. Explanted valves that are not sent to a pathologist (i.e., in some cases where there is no notable tissue on the valve) are kept in formalin solution and

maintained in the FER laboratory at St. Jude Medical as described in paragraph 1 above.

12. On occasion, St. Jude Medical is asked by a hospital or patient to return an explanted valve that has been sent to St. Jude Medical. Such explanted valves are sometimes returned pursuant to such requests upon agreement. St. Jude Medical documents such requests and its compliance if the valve is returned. Prior to returning any explanted Silzone® coated heart valve, St. Jude Medical shall notify Plaintiffs in writing of the intended return and provide Plaintiffs with a reasonable opportunity to inspect such valve. Plaintiffs' inspection may include inspection by an expert designated by Plaintiffs' counsel at such expert's testing facility.

13. Notwithstanding any other provision of this Protocol, neither St. Jude Medical nor Plaintiffs may undertake any "Destructive Testing" procedure with respect to any Silzone coated heart valve unless the party proposing such testing shall have provided the other party with at least thirty (30) days written notice of such testing and shall have afforded such other party the right to designate an expert to be present during and observe such testing. "Destructive Testing" means any testing requiring either (i) disassembly of the valve, (ii) detachment or cutting of the valve's sewing cuff (beyond that necessary for biopsies to be taken under Paragraph 9 above) or (iii) coating of the valve in preparation for scanning electron microscopy.